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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,705	06/01/2001	William J. Roberts	1400-002	2502

7590 02/24/2003

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,705

Applicant(s)

ROBERTS, WILLIAM J.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 3-7, 11-13, 15-21, 29-33, 38-40 and 42-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 9, 10, 14 is/are allowed.
- 6) ☐ Claim(s) 1, 2, 8, 34-37, 41 and 49-61 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☐ Claim(s) are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) ☐ Other:

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Invention: *The invention is directed to compounds and methods for supplementing the concentration of parent androgen by administering the compound such as testosterone, 5a-androst-1-en-3-one, a precursor to the steroid hormone 17b-hydroxy-5a-androst-1-en-3-one for increasing the level of this hormone in humans.*

Status of the Application

Acknowledgement is made of election of species testosterone with traverse filed in paper no. 9. Traversal is on the basis that the search for all the invention as presently claimed will not be a burden on the examiner. Examiner respectfully disagrees because of the reason set forth in our previous office action. See also MPEP 802.02. Claims 1-61 are pending. Claims 1, 2, 8, 34-37 and 49-61 are examined. Others are withdrawn from consideration as non-elected invention. No claim is allowed at this time.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2, 8-10,14, 22-28, 34-37, 41 and 49-61 rejected under 35 U.S.C. 102(b) as being anticipated by Arnold (US 5,880,117) and Mattern et al. (US 5,578,588). See 3-55 in col. 2 and claims in US 588 and lines 3-63 in col. 2 and claims. Androst-4-ene-3.beta.,17.beta.-diol (7CI, 8CI). 4-androstenediol for increase of testosterone levels in humans, see US '117, see claims lines 14-29, and 37-64 in col. 2.

OTHER NAMES:

CN. DELTA.4-Androstene-3.beta.17.beta. -Diol

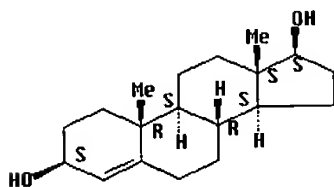
CN 3.beta.17.beta. -Dihydroxy-4-androstene

CN 4-Androstenediol

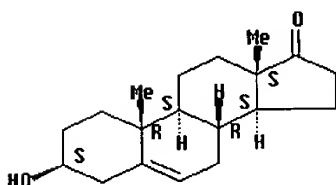
FS STEREOSEARCH

MF C19 H30 O2

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2. DHEA, which is a testosterone precursor. See US '588. especially claims.



RN 53-43-0 REGISTRY

CN Androst-5-en-17-one, 3-hydroxy-, (3.beta.)- (9CI) (CA INDEX NAME)

OTHER CA INDEX NAMES:

CN Androst-5-en-17-one, 3.beta. -hydroxy- (8CI)

OTHER NAMES:

CN DELTA.5-Androsten-3.beta. -ol-17-one

CN 17-Chetovis

CN 17-Hormoforin

CN 3.beta. -Hydroxy-.DELTA.5-androsten-17-one

CN 3.beta.-Hydroxyandrost-5-en-17-one

CN 3.beta.-Hydroxyandrost-5-ene-17-one

CN 5,6-Dehydroisoandrosterone

CN 5,6-Didehydroisoandrosterone

CN 5-Androsten-3.beta.-ol-17-one

CN 5-Dehydroepiandrosterone

CN Androst-5-ene-3.beta.-ol-17-one

CN Androstenedione
CN Astenile
CN Deandros
CN Dehydro-epi-androsterone
CN Dehydroepiandrosterone
CN Dehydroisoandrosterone
CN DHA
CN DHEA
CN Diandron
CN Diandrone
CN GL 701
CN IM 28
CN Prasterone
CN Psicosterone
CN trans-Dehydroandrosterone

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

February 23, 2003


SABIHA QAZI, PH.D
PRIMARY EXAMINER